

K963221

JAN 13 1997

**SUMMARY OF SAFETY AND EFFECTIVENESS**

(As required by 21 CFR 807.92)

JAN 10 1997

**1. General Information**

Classification: Class II  
Image Assisted Surgery Device

Common/Usual Name: Image Assisted Surgery Device Option

Proprietary Name: ViewPoint - Optical Digitizer Option

Establishment Registration: Picker International, Inc.  
World Headquarters  
595 Miner Road  
Highland Heights, Ohio 44143  
FDA Owner Number: #1580240  
FDA Registration Number: #1525965

Performance Standards: No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

The device does comply with the draft voluntary industry standard titled "Neurological Standard for Image-Interactive Stereotactic and Localization Systems (ASTM 10th Draft 9/94)."

**2. Intended Uses**

The Optical Digitizer Option for ViewPoint does not change the intended use of the ViewPoint system.

The ViewPoint is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-cranial surgical procedures involving space occupying lesions or malformations (including soft tissue, vascular and osseous).

**3. Device Description**

The Optical Digitizer Option uses infrared emitting diodes to determine the position and orientation of the probe during intra-operative localization. This option has accuracy and resolution similar to that provided with the ultrasonic digitizer currently used with ViewPoint.

**4. Safety and Effectiveness**

The ViewPoint System with the Optical Digitizer Option is substantially equivalent to the ViewPoint System described in the 510(k) K961168 in safety and effectiveness. The following chart has been compiled to demonstrate the Optical Digitizer's substantial equivalence to this device.

**SUBSTANTIAL EQUIVALENCE CHART**

<b>Parameter</b>	<b>ViewPoint with Optical Digitizer Option</b>	<b>Predicate Device ViewPoint (K961168)</b>
Type of Digitizer	Infrared signals emitted from diodes on a hand-held wand are detected by a Position Sensor Assembly with two optical detectors. The assembly is either on a mobile pedestal, mounted to the OR table or mounted to the ceiling.	Ultrasonic pulses emitted from two locations on a hand-held wand are detected by four microphones in a detector array which is mounted to the OR table.
Active Digitizer Volume	Silo shape, with 1 meter diameter and 1 meter length.	0.75 cubic meter (26.5 cu. ft.)
Max. Digitizer Rate	30 Hz for one or two tools; for three tools, the rate is 30 Hz for one of the tools and 15 Hz for the other two.	100 pts/sec/emitter
Wand/Localizer Average Accuracy	Same	2.0 - 5.0 mm
Registration Technique	Same	Scanned Fiducials
Type of Sterilization	Same	Wand is ETO Sterilizable.

<b>Parameter</b>	<b>ViewPoint with Optical Digitizer Option</b>	<b>Predicate Device ViewPoint (K961168)</b>
Computer	Same	A superscalar RISC microprocessor with sufficient RAM memory and image storage capabilities. Single high resolution monitor. Networking capabilities which support DICOM v3.0.
Operating Software	Same operating software, selections for the optical wands and Position Sensor Assembly have been added.	Operating software uses a graphical user interface to facilitate user interaction. Multiplanar reformatting and surface rendering capabilities included. Software is able to show diagnostic images at the location of the probe tip.
Intended Use	The Optical Digitizer Option for ViewPoint does not change the intended use of the ViewPoint system.	The ViewPoint is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-cranial surgical procedures involving space occupying lesions or malformations (including soft tissue, vascular and osseous).